Title: **Internal and External Audit Checklist** - QMS-MD Medical Devices CONFIDENTIAL

This checklist is based on the Quality System Regulation (FDA 21 CFR Part 820), ISO 13485:2003 and the Medical Device Directive (MDD 93/42/EEC-2007/47/EC). Refer to Bose QMS-MD Operating Procedure OP00016 for additional information. Complete sections I through IV below (select N/A "not applicable" for any areas not relevant to the audit).

I. Audit Type (Check One):	Internal ☐ (*If Internal, complete section II below*)	External ☐ (*If external, complete section III below*)
II. Audit Start Date:		
Audit End Date:		
Bose Auditor Name:		
Area or Department under review:		
Facility Address:		
Auditee Name / Title:		
Product Type / Category:		
Quality Manual *(Document Number, Issue Date):*		
III. Audit Start Date:		
Audit End Date:		
Bose Auditor Name:		
External Group Name:		
Facility Address:		
Company Representative:		
Representative Title:		
Product Type / Category:		
Quality Manual *(Number, Issue Date):*		
Document # :		
IV. Comments:		

Overview: The audit process will consist of a review of company documentation, as well as staff interviews, related to the organization's quality system. Examples of documentation will be reviewed as objective evidence to confirm the quality systems compliance. Only those elements relevant to a particular area or vendor will be reviewed. Once complete, an audit report will be generated which may be used to identify and address any non-conformances noted.

Audit Confidentiality: Information obtained from this audit and reviewed in the course of producing this report will be treated as confidential by Bose. It will shared internally based on need-to-know and externally upon request by 3rd party regulatory agencies or notified body.

V. Audit Scope			***(Select Y (Yes) or N (No) for each element of the quality system covered by this audit.***
Clause		Description	Audit (Y/N)
4		**Quality management system**	
4.1		General requirements	
4.2		Documentation requirements	
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	4.2.2	Quality manual	
	4.2.3	Control of documents	
	4.2.4	Control of records	
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5.1		Management commitment	
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5.4		Planning	
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	5.4.2	Quality management system planning	
5.5		Responsibility authority and communication	
	5.5.1	Responsibility and authority	
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	5.5.3	Internal communication	
5.6		Management review	
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6			**Resource Management**	
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	6.2		Human resources	
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7			**Product realization**	
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		7.2.2	Review of requirements related to the product	
		7.2.3	Customer communication	
	7.3		Design and development	
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		7.3.2	Design and development inputs	
		7.3.3	Design and development outputs	
		7.3.4	Design and development review	
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			7.5.1.2.2 Installation activities	
			7.5.1.2.3 Servicing activities	
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		7.5.3	Identification and traceability	
		7.5.3.1	Identification	
		7.5.3.2	Traceability	
			7.5.3.2.1 General	
			7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices	
		7.5.3.3	Status identification	
		7.5.4	Customer property	
		7.5.5	Preservation of product	

	7.6		Control of monitoring and measuring equipment	
8			**Measurement, analysis and improvement**	
	8.1		General	
	8.2		Monitoring and measurement	
		8.2.1	Customer service feedback	
		8.2.2	Internal audit	
		8.2.3	Monitoring and measurement of processes	
		8.2.4	Monitoring and measurement of product	
		8.2.4.1	General requirements	
		8.2.4.2	Particular requirements for active implantable medical devices and implantable medical devices	
	8.3		Control of nonconforming product	
	8.4		Analysis of data	
	8.5		Improvement	
		8.5.1	Continual improvement general	
		8.5.2	Corrective action	
		8.5.3	Preventive action	

Q#/QSR	Clause Text	Sample Audit Question	Evidence
	4 Quality management system		
	4.1 General requirements		
4.1q1 820.5	The organization shall establish, document, implement and maintain a quality management system and maintain (continually improve) its effectiveness in accordance with the requirements of this International Standard.	Has Organization established, documented, implemented and maintained a QMS and maintained (continually improved) its effectiveness in accordance with ISO 13485? (Questions in section 4.1 are verified throughout the audit)	
4.1q2a 820.5	The organization shall a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),	Where has Organization identified the processes needed for the QMS and their application throughout the organization? (See 4.2.2)	
4.1q2b 820.5	The organization shall b) determine the sequence and interaction of these processes,	Where has Organization determined the sequence and interaction of QMS processes? (See 4.2.2)	
4.1q2c 820.5	The organization shall c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,	What are the criteria and methods Organization uses to ensure that the operation and control of QMS processes are effective?	
4.1q2d 820.5	The organization shall d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,	Has Organization provided resources and information needed to support the operation and monitoring of QMS processes? (See section 6)	
4.1q2e 820.5	The organization shall e) monitor, measure and analyze these processes, and	How does Organization monitor, measure and analyze QMS processes? (See section 8)	
4.1q2f 820.5	The organization shall f) implement actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of these processes.	How has Organization implemented actions necessary to achieve planned results and maintain the effectiveness (continual improvement) of processes needed for the QMS?	
4.1q3 820.5	These processes shall be managed by the organization in accordance with the requirements of this International Standard.	Are processes needed for the QMS managed by the organization in accordance with the requirements of ISO 13485?	
4.1q4 820.5	Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes.	When Organization outsources any process that affects product conformity with requirements, how is control ensured over such processes? (See 7.4)	
4.1q5 820.5	Control of such outsourced processes shall be identified within the quality management system (see 8.5.1).	Where is the control of outsourced processes that affect product conformity with requirements identified within the QMS? (See 7.4)	
	NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.		

Q#/QSR	Clause Text	Sample Audit Question	Evidence
	4.2 Documentation requirements		
	4.2.1 General		
4.2.1q1a 820.181, 820.184, 820.186	The quality management system documentation shall include a) documented statements of a quality policy and quality objectives, b) a quality manual, c) documented procedures required by this International Standard, d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and e) records required by this International Standard (see 4.2.4). f) any other documentation specified by national or regional regulations.	Does Organization have documented statements of a quality policy and quality objectives? (See 5.3, 5.4.1) Does Organization have a quality manual? Does Organization have the documented procedures required by ISO 13485? Are adequate documents in place to ensure the effective planning, operation and control of Organization's processes? Does documentation include the records required by ISO 13485? Are there any documents required by regulations?	
	Where this International Standard specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.	(Verify throughout audit)	
	For each type or model of medical device, the organization shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements (see 4.2.3).	Can you show me a **file** for each type or model of medical device containing or identifying documents with product specifications and QMS requirements?	
	These documents shall define the complete manufacturing process and, if applicable, installation and servicing.	(Review documents to verify they define the complete manufacturing process, installation and servicing)	
MDD	Does the retention period of documents describe requirements for Annex II, 6.1 (declaration of conformity, documentation on the quality system, decisions of the Notified Body, design dossier/technical documentation) and does the description comply with the requirements for 5 years after the last product has been manufactured?	I	

	4.2.2 Quality manual	

4.2.2q1a	The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, including details of and justification for any exclusions and/or non-application (see 1.2), b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.	Where in the quality manual is the scope of the QMS identified, including details of and justification for exclusions and/or requirements that don't apply? Where does the quality manual contain or reference the documented procedures established for the QMS? Where does the quality manual include a description of the interaction between the processes of the QMS?	
	The quality manual shall outline the structure of the documentation used in the quality management system.	Where does the quality manual outline the documentation structure of the QMS?	

	4.2.3 Control of documents		
4.2.3q1 820.40	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.	How are the documents required by the QMS controlled? (Documents to be reviewed throughout the audit)	
4.2.3q2 820.40	A documented procedure shall be established to define the controls needed a) to review and approve documents for adequacy prior to issue, b) to review and update as necessary and re-approve documents? c) to ensure that changes and the current revision status of documents are identified? d) to ensure that relevant versions of applicable documents are available at points of use? e) to ensure that documents remain legible and readily identifiable? f) to ensure that documents of external origin are identified and their distribution controlled? g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	Can you show me a **documented procedure** that defines the controls needed for each of the following? a) review and approve documents for adequacy prior to issue? b) review and update as necessary and re-approve documents? c) ensure that changes and the current revision status of documents are identified? d) ensure that relevant versions of applicable documents are available at points of use? e) ensure that documents remain legible and readily identifiable? f) ensure that documents of external origin are identified and their distribution controlled? g) prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.	
	The organization shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.		
	The organization shall define the period for which at least one copy of obsolete controlled documents shall be retained.		

	This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record (see 4.2.4), or as specified by relevant regulatory requirements.		
MDD	Is the product related documentation an integrated part of the quality system. Such as 1) Annex II, 3.2; 2) Annex III, 3; 3) Annex VII, 3		
	4.2.4 Control of records		
4.2.4q1 820.180	Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.	What records exist that provide evidence of conformity to requirements and of the effective operation of the QMS? (Should be reviewed throughout the audit)	
4.2.4q2 820.180	Records shall remain legible, readily identifiable and retrievable.	Are records legible, readily identifiable and retrievable? (Should be reviewed throughout the audit)	
4.2.4q3 820.180	A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.	Does Organization have a **documented procedure** defining the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?	
	The organization shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release by the organization or as specified by relevant regulatory requirements.		

	5 Management responsibility		
	5.1 Management commitment		
5.1q1a 820.20a)	Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining (continually improving) its effectiveness by a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing the quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.	How does top management communicate the importance of meeting customer and legal requirements to the organization? Has a company quality policy been established? (See 5.3) What are the quality objectives established by top management? (See 5.4.1) Does top management conduct management reviews? (See 5.6) How does top management ensure the availability of resources to support and continually improve the QMS?	
MDD	Are measures implemented to verify and improve the effectiveness of the Q-system? If applicable – requirements of the Medical Device Directive concerning 1) design dossier, 2) design reviews, 3) product quality, 4) control of nonconforming product, etc.?		

	5.2 Customer focus		
5.2q1	Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 & 8.2.1).	How does top management ensure that customer requirements are determined and met?	

	5.3 Quality policy		
5.3q1a 820.20a)	Top management shall ensure that the quality policy a) is appropriate to the purpose of the organization, b) includes a commitment to comply with requirements and to maintain (continually improve) the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.	How does top management ensure that the quality policy is appropriate to the purpose of the organization? Does the quality policy include a commitment to comply with requirements and to maintain (continually improve) QMS effectiveness? Are the contents of the quality policy relevant to Organization, and measurable? Is the quality policy communicated and understood within the organization? Is there an established process to review the quality policy for continuing suitability?	

	5.4 Planning		
	5.4.1 Quality objectives		
5.4.1q1 820.20a)	Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization.	Has top management established quality objectives (including those needed to meet requirements for product) at relevant functions and levels within the organization?	
5.4.1q2 820.20a)	The quality objectives shall be measurable and consistent with the quality policy.	Are the quality objectives consistent with the quality policy? What are the measurements?	
	5.4.2 Quality management system planning		
5.4.2q1 820.5d)	Top management shall ensure that a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	How do you ensure that the planning of the QMS is carried out in order to meet the requirements given in ISO 13485, as well as the quality objectives? How do you ensure that the integrity of the QMS is maintained when changes to the QMS are planned and implemented?	

	5.5 Responsibility, authority and communication		
	5.5.1 Responsibility and authority		
5.5.1q1 820.20b)	Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization.	How are responsibilities and authorities defined, **documented** and communicated within the organization? (Verify throughout audit)	
	Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.		
	NOTE National or regional regulations might require the nomination of specific persons as responsible for activities related to monitoring experience from the post-production stage and reporting adverse events (see 8.2.1 and 8.5.1).		
	5.5.2 Management representative		

5.5.2q1a 820.20b)	Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes a) ensuring that processes needed for the quality management system are established, implemented and maintained, b) reporting to top management on the performance of the quality management system and any need for improvement (see 8.5), and c) ensuring the promotion of awareness of regulatory and customer requirements throughout the organization.	Who is your Quality Management System Management Representative? Does the management representative have responsibility and authority to a) ensure that processes needed for the QMS are established, implemented and maintained? b) report to top management on the performance of the QMS and any need for improvement? c) ensure the promotion of awareness of regulatory and customer requirements throughout the organization?	
	NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.		

	5.5.3 Internal communication		
5.5.3q1 820.20b)	Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.	How is information regarding the effectiveness of the QMS communicated within the organization?	

	5.6 Management review		
	5.6.1 General		
5.6.1q1 820.20c)	Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness.	What is the frequency that top management reviews the organization's QMS?	
5.6.1q2 820.20c)	This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.	What kinds of information are reviewed in management reviews? (must include suitability, adequacy and effectiveness of QMS; improvement; & changes to the QMS, quality policy and objectives)	
5.6.1q3 820.20c)	Records from management reviews shall be maintained (see 4.2.4).	Can you show me **records** from recent management reviews?	

	5.6.2 Review input		
5.6.2q1	The input to management review shall include information on a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement, and h) new or revised regulatory requirements.	Can you show me that each of the following were included in review(s)? a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement, and h) new or revised regulatory requirements.	

	5.6.3 Review output		
5.6.3q1	The output from the management review shall include any decisions and actions related to a) improvement needed to maintain the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	What decisions or actions have resulted from management reviews for each of the following? a) improvement needed to maintain the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.	
	6 Resource management		
	6.1 Provision of resources		
6.1q1 820.20b)	The organization shall determine and provide the resources needed a) to implement (and maintain) the quality management system and maintain (continually improve) its effectiveness, and b) to meet regulatory and (enhance customer satisfaction by meeting) customer requirements.	What resources has Organization provided to implement and maintain the QMS and continually improve its effectiveness? What resources has Organization provided to ensure that customer and regulatory requirements are met? (See 6.2, 6.3, 6.4)	

	6.2 Human resources		
	6.2.1 General		
6.2.1q1 820.20b) 820.25a), b)	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.	What are the education, training, skills and experience required by this job/task? How does this person meet those qualifications?	
	6.2.2 Competence, awareness and training		
6.2.2q1 820.20b), 820.25a), b)	The organization shall a) determine the necessary competence for personnel performing work affecting product quality, b) provide training or take other actions to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and e) maintain appropriate records of education, training, skills and experience (see 4.2.4).	How do you determine the necessary education, training, skills and experience for people performing work affecting product quality? What training or other actions do you provide to satisfy the needs of personnel? When you provide training or other actions to satisfy competence needs, how do you evaluate the effectiveness of those actions? (records) (Sample throughout organization) How do your activities contribute to the achievement of quality objectives? Where do you maintain **records** of education, training, skills and experience?	
	NOTE National or regional regulations might require the organization to establish documented procedures for identifying training needs.		
	6.3 Infrastructure		

6.3q1 820.70d), f), g), 1), 2), 3), h)	The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable a) buildings, workspace and associated utilities, b) process equipment (both hardware and software), and c) supporting services (such as transport or communication).	Are the buildings, workspace, and utilities appropriate to meet product requirements? How are they maintained? What kind of process equipment (both hardware and software) is necessary to conform to product requirements? How is the equipment maintained? What supporting services (such as transport or communication) are needed to ensure that product meets requirements? How are they maintained?	
	The organization shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.	**documented requirements**	
	Records of such maintenance shall be maintained (see 4.2.4).	**Records**	

	6.4 Work environment		
6.4q1 820.70c), d), e)	The organization shall determine and manage the work environment needed to achieve conformity to product requirements.	What kind of work environment is required to achieve conformity to product requirements? How is this environment managed and maintained?	

	The following requirements shall apply. a) The organization shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product (see 7.5.1.2.1). b) If work environment conditions can have an adverse effect on product quality, the organization shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions (see 7.5.1.2.1). c) The organization shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person [see 6.2.2 b)]. d) If appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel (see 7.5.3.1).	**Documented requirements and work instructions**	

	7 Product realization		
	7.1 Planning of product realization		
7.1q1 820.5	The organization shall plan and develop the processes needed for product realization.	Where are the processes needed for product realization identified?	
7.1q2 820.5	Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).	Is the planning of product realization consistent with the requirements of the other processes of the QMS? (Verify there are no inconsistencies or conflicts between quality system procedures)	
7.1q3 820.5	In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes, documents, and provide resources specific to the product; c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).	Where in the product realization process do you determine the quality objectives and requirements for products? When planning for product realization, how do you establish processes, documents, and provide resources specific to the product How do you determine verification, validation, monitoring, inspection and test activities specific to the product, and the criteria for product acceptance? What **records** exist showing that both the realization processes and the product meet requirements?	
7.1q4 820.5	The output of this planning shall be in a form suitable for the organization's method of operations.	What are the outputs of product realization planning? Are they in a form suitable for Organization?	
	The organization shall establish documented requirements for risk management throughout product realization.	**documented requirements** for risk management	
	Records arising from risk management shall be maintained (see 4.2.4).	**records**	
	NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.		
	NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.		
	NOTE 3 See ISO 14971 for guidance related to risk management.		

	7.2 Customer-related processes		
	7.2.1 Determination of requirements related to the product		
7.2.1q1a	The organization shall determine a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	How does Organization determine each of the following requirements? a) requirements specified by the customer, including the requirements for delivery and post-delivery activities, b) requirements not stated by the customer but necessary for specified or intended use, where known, c) statutory and regulatory requirements related to the product, and d) any additional requirements determined by the organization.	
	7.2.2 Review of requirements related to the product		
7.2.2q1	The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that a) product requirements are defined and documented, b) contract or order requirements c) the organization has the ability to meet the defined requirements.	What kind of review is done to ensure that the organization has the ability to meet requirements before committing to supply product? How do you ensure that product requirements are defined, **documented**, and reviewed before committing to supply product? How do you ensure that contract or order requirements differing from those previously expressed are resolved before committing to supply product?	
7.2.2q2	Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).	Can you show me records of the product requirement review results and actions resulting from them?	
7.2.2q3	Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.	When customers don't have documented requirements, how do you confirm their requirements before accepting orders?	
7.2.2q4	Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.	When product requirements are changed, how do you ensure that relevant documents are changed and that relevant personnel are made aware of the changes?	
	NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.		

	7.2.3 Customer communication	

7.2.3q1	The organization shall determine and implement effective arrangements for communicating with customers in relation to a) product information, b) enquiries, contracts or order c) customer feedback, including customer complaints (see 8.2.1), and d) Advisory notices (see 8.5.1).	What method(s) are used to communicate with customers regarding - product information? - enquiries, contracts, or order handling, including amendments? - feedback, including customer complaints? - Advisory notices?	

	7.3 Design and development		
	7.3.1 Design and development planning		
	The organization shall establish documented procedures for design and development.	**documented procedures**	
7.3.1q1 820.30a), b), j)	The organization shall plan and control the design and development of product.	Can you explain to me the process used by Organization to plan and control the design and development of product?	
7.3.1q2 820.30a), b), j)	During the design and development planning, the organization shall determine a) the design and development stages, b) the review, verification, validation and design transfer activities (see Note) that are appropriate to each design and development stage, and c) the responsibilities and authorities for design and development.	What are the stages in the design and development process? How do you determine the review, verification, validation, and design transfer activities appropriate to each design and development stage? How/where are design and development responsibilities and authorities defined?	
7.3.1q3 820.30a), b), j)	The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.	How does Organization ensure effective communication and clear assignment of responsibility between different groups involved in design and development?	
7.3.1q4 820.30a), b), j)	Planning output shall be documented, and updated as appropriate, as the design and development progresses (see 4.2.3).	As product design and development progresses, how are the planning outputs **documented** and updated?	
	NOTE Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.		

	7.3.2 Design and development inputs		
7.3.2q1a 820.30c)	Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include a) functional, performance and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and d) other requirements essential for design and development, and e) output(s) of risk management (see 7.1).	What are the design inputs relating to each of the following product requirements? a) functional, performance and safety requirements, according to the intended use, b) applicable statutory and regulatory requirements, c) where applicable, information derived from previous similar designs, and f) other requirements essential for design and development, and d) output(s) of risk management. Where are they **recorded**?	
7.3.2q2 820.30c)	These inputs shall be reviewed for adequacy and approved.	How & when are the design and development inputs reviewed and approved for adequacy?	
7.3.2q3 820.30c)	Requirements shall be complete, unambiguous and not in conflict with each other.	How does Organization ensure that requirements are complete, unambiguous and don't conflict with each other?	
MDD	Are all requirement of the Medical Device Directive (MDD) taken into consideration?		
MDD	Is the result of the development documented according to the requirements of the MDD Annex II.3 and does this documentation include 1) general description of the product, 2) design documents, 3) harmonized standards used, 4) risk analysis, 5) essential requirements, 6) Clinical Data/Evaluation, 7) draft labeling and instructions for use? Also, evidence that the Essential Requirements are fulfilled if connected to other devices within the intended use?		
	7.3.3 Design and development outputs		
7.3.3q1 820.30d)	The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.	How can design and development outputs be verified against the inputs? (see 7.3.5q1) Are these outputs approved prior to release?	

7.3.3q2 820.30d)	Design and development outputs shall a) meet the input requirements for design and development, b) provide appropriate information for purchasing, production and for service provision, c) contain or reference product acceptance criteria, and d) specify the characteristics of the product that are essential for its safe and proper use.	Can you show me examples of design and development outputs and how they meet the input requirements? What outputs include information for purchasing, production and service? Where are product acceptance criteria specified? Where are product characteristics needed for safe and proper use specified?	
	Records of the design and development outputs shall be maintained (see 4.2.4).	Where are **records** of design and development maintained?	
MDD	Is there procedures for the development of data for technical files?		
MDD	Is there evidence of an adequate technical documentation in accordance with Annex VII, clause 3; or Annex II, clause 3?		
MDD	Are copies of labels retained as part of the technical documentation?		
MDD	Is there an appropriate provision for translation into the language of the target market and are copies of translated labels controlled?		
MDD	Are labels reviewed to ensure that the labels comply with the relevant provisions of Annex I, clause 13 of the Medical Device Directive?		
MDD	Does the manufacturer retain a record (list) of all devices to which CE marking is to be affixed?		
MDD	Is there a procedure that this record is a controlled document?		
MDD	Is it ensured that the certification agency is informed prior to major changes to the product technology covered by the conformity assessment?		
	NOTE Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.		

	7.3.4 Design and development review		
7.3.4q1a 820.30e)	At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1) a) to evaluate the ability of the results of design and development to meet requirements, and b) to identify any problems and propose necessary actions.	At what stages of design and development do you perform reviews to evaluate if the results meet requirements? (See 7.3.1q2b) Can you show me some problems that have been identified and actions proposed at these reviews?	
7.3.4q2 820.30e)	Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel (see 5.5.1 and 6.2.1).	What functions (including specialists) are represented at these reviews? At each stage, are all functions concerned with that stage represented?	
7.3.4q3 820.30e)	Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).	Can you show me **records** of the results of the reviews and any necessary actions taken?	
	7.3.5 Design and development verification		
7.3.5q1 820.30f)	Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements.	What verification activities are performed to ensure that the design and development outputs have met the input requirements? (See 7.3.3q1)	
7.3.5q2 820.30f)	Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).	Can you show me **records** of the results of the verification activities and resulting actions?	
MDD	Are Clinical Investigations required or are there adequate provisions for compiling the clinical data?		
	Does a Declaration of Conformity covering all devices exist?		
	Are there provisions for issuing the D of C?		
	7.3.6 Design and development validation		
7.3.6q1 820.30g)	Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, (where known).	What design and development validation activities are performed to ensure that the product is capable of meeting the requirements for the intended use?	

7.3.6q2 820.30g)	(Wherever practicable,) validation shall be completed prior to the delivery or implementation of the product (see Note 1).	Do records show that validation is done before product shipment? If not, is the justification recorded?	
7.3.6q3 820.30g)	Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).	Can you show me **records** of the validation activity results and any follow-up actions?	
	As part of design and development validation, the organization shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations (see Note 2).		
	NOTE 1 If a medical device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.		
	NOTE 2 Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.		

	7.3.7 Control of design and development changes		
7.3.7q1 820.30i)	Design and development changes shall be identified and records maintained.	How are design and development changes identified? Where are the **records** kept?	
7.3.7q2 820.30i)	The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation.	Are changes reviewed, verified, validated, and approved before implementation?	
7.3.7q3 820.30i)	The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.	Can you show me evidence that the review of design and development changes includes evaluation of the effect on component parts and products in the field?	
7.3.7q4 820.30i)	Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).	Can you show me **records** of the results of change reviews and any necessary actions?	

	7.4 Purchasing		
	7.4.1 Purchasing process		
7.4.1q1 820.50a)	The organization shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.	How do you ensure that purchased product conforms to specified requirements? Can you show me a **documented procedure** for this?	
7.4.1q2 820.50a)	The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.	How do you determine the type and extent of control applied to the supplier and the purchased product?	
7.4.1q3 820.50a)	The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements.	How do you evaluate and select suppliers? (based on their ability to supply product in accordance with Organization's requirements)	
7.4.1q4 820.50a)	Criteria for selection, evaluation and re-evaluation shall be established.	Can you show me the criteria for selection, evaluation and re-evaluation of suppliers?	
7.4.1q5 820.50a)	Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).	Can you show me **records** of the results of supplier evaluations and any necessary actions? (verify that criteria have been met)	
	7.4.2 Purchasing information		
7.4.2q1 820.50b)	Purchasing information shall describe the product to be purchased, including where appropriate a) requirements for approval of product, procedures, processes and equipment, b) requirements for qualification of personnel, and c) quality management system requirements.	Do orders/contracts include requirements for approval of product, procedures, processes and equipment? Do require any qualification of supplier personnel? If so, can you show where the requirement is documented? Do you have any QMS requirements of your suppliers? If so, can you show me where they are required?	
7.4.2q2 820.50b)	The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.	How does Organization ensure the adequacy of purchasing requirements before communicating them to the supplier?	
	To the extent required for traceability given in 7.5.3.2, the organization shall maintain relevant purchasing information, i.e. documents (see 4.2.3) and records (see 4.2.4).	**documents and records**	
	7.4.3 Verification of purchased product		
7.4.3q1 820.80b)	The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.	What inspection or other activities are used to ensure that purchased product meets your purchasing requirements?	
7.4.3q2 820.80b)	Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.	Do you ever perform product verification at the supplier's site? If so, where are the verification arrangements and method of product release identified?	
	Records of the verification shall be maintained (see 4.2.4).	Can you show me **records** of onsite verification?	

	7.5 Production and service provision		
	7.5.1 Control of production and service provision		
	7.5.1.1 General requirements		
7.5.1q1 820.70a)	The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable a) the availability of information that describes the characteristics of the product, b) the availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary, c) the use of suitable equipment, d) the availability and use of monitoring and measuring devices, e) the implementation of monitoring and measurement, and f) the implementation of release, delivery and post-delivery activities, and g) the implementation of defined operations for labelling and packaging.	When carrying out production (or service) are <u>all</u> of the following controlled conditions in place? a) Is information that describes the characteristics of the product available? b) Are appropriate documented procedures, documented requirements, work instructions, reference materials and reference measurement procedures available (if needed)? c) Is suitable equipment used for carrying out production (or service)? d) Are appropriate gages, etc. used in production (or service)? (See 7.6) e) Are appropriate kinds of monitoring and measurement done? (See 8.2.4) f) Are proper release, delivery and post-delivery activities in place? g) Are packaging and labeling operations defined and implemented?	
820.184	The organization shall establish and maintain a record (see 4.2.4) for each batch of medical devices that provides traceability to the extent specified in 7.5.3 and identifies the amount manufactured and amount approved for distribution.	**record**	
	The batch record shall be verified and approved.		
	NOTE A batch can be a single medical device.		
	7.5.1.2 Control of production and service provision — Specific requirements		
	7.5.1.2.1 Cleanliness of product and contamination control		
820.70b), c), d), e), f), g), 1), 2), 3), h), i), 820.170, 820.200	The organization shall establish documented requirements for cleanliness of product if a) product is cleaned by the organization prior to sterilization and/or its use, or b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or c) product is supplied to be used non-sterile and its cleanliness is of significance in use, or d) process agents are to be removed from product during manufacture.	**documented requirements** for cleanliness of product	
	If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4 a) and 6.4 b) do not apply prior to the cleaning process.		

	7.5.1.2.2 Installation activities		
	If appropriate, the organization shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.	**documented requirements** with acceptance criteria for installing and verifying the installation	
	If the agreed customer requirements allow installation to be performed other than by the organization or its authorized agent, the organization shall provide documented requirements for installation and verification.	**documented requirements** for installation and verification if installation is performed by outside org.	
	Records of installation and verification performed by the organization or its authorized agent shall be maintained (see 4.2.4).	**Records** of installation and verification	
	7.5.1.2.3 Servicing activities		
	If servicing is a specified requirement, the organization shall establish documented procedures, work instructions and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.	**documented procedures, work instructions and reference materials and reference measurement procedures**	
	Records of servicing activities carried out by the organization shall be maintained (see 4.2.4).	**Records** of servicing activities	
	NOTE Servicing can include, for example, repair and maintenance.		
	7.5.1.3 Particular requirements for sterile medical devices		
820.70b), c), d), e), f), g), 1), 2), 3), h), i), 820.170, 820.200	The organization shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch (see 4.2.4).	**records** of the process parameters for the sterilization process	
	Sterilization records shall be traceable to each production batch of medical devices (see 7.5.1.1).	Sterilization traceability **records**	

	7.5.2 Validation of processes for production and service provision		
	7.5.2.1 General requirements		
7.5.2q1 820.75	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.	Do you have any production or service processes where the resulting output cannot be verified later? If so, how to you validate them?	
7.5.2q2 820.75	Validation shall demonstrate the ability of these processes to achieve planned results.	Can you show me records that demonstrate that the validation done has met the requirements?	
7.5.2q3a 820.75	The organization shall establish arrangements for these processes including, as applicable a) defined criteria for review and approval of the processes, b) approval of equipment and qualification of personnel, c) use of specific methods and procedures d) requirements for records (see 4.2.4), and e) revalidation.	How are these special processes reviewed and approved? Can you show me records of personnel and equipment qualification? Where are specific methods and procedures defined? Can you show me **records** for these processes? When changes are made to processes, how do you revalidate them?	
	The organization shall establish documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements.	**documented procedures** for validation of computer software	
	Such software applications shall be validated prior to initial use.		
	Records of validation shall be maintained (see 4.2.4).	**Records** of validation	
	7.5.2.2 Particular requirements for sterile medical devices		
	The organization shall establish documented procedures for the validation of sterilization processes.	**documented procedures** for the validation of sterilization processes	
	Sterilization processes shall be validated prior to initial use.		
	Records of validation of each sterilization process shall be maintained (see 4.2.4).	**Records** of validation of each sterilization process	

	7.5.3 Identification and traceability	**7.5.3 Identification and traceability**	
	7.5.3.1 Identification		
7.5.3q1 820.60	(Where appropriate,) the organization shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.	How do you identify product throughout your processes? (Verify in production, storage, segregation areas, etc.) Can you show me **documented procedures** for this?	
	The organization shall establish documented procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product [see 6.4 d)].	**documented procedures**	
	7.5.3.2 Traceability		
	7.5.3.2.1 General		
820.65	The organization shall establish documented procedures for traceability.	**documented procedures** for traceability	
	Such procedures shall define the extent of product traceability and the records required (see 4.2.4, 8.3 and 8.5).		
7.5.3q3	Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).	Can you show me unique identification **records** for products requiring traceability?	
	NOTE In some industry sectors, configuration management is a means by which identification and traceability (are) can be maintained.		
	7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices		
	In defining the records required for traceability, the organization shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.	**records** of all components, materials and work environment conditions	
	The organization shall require that its agents or distributors maintain records of the distribution of medical devices to allow traceability and that such records are available for inspection.		
	Records of the name and address of the shipping package consignee shall be maintained (see 4.2.4).	**Records** of the name and address of consignee	

	7.5.3.3 Status identification		
7.5.3q2 820.80e) 820.86	The organization shall identify the product status with respect to monitoring and measurement requirements.	How is product inspection status identified? (Verify in production, storage, segregation areas, etc.)	
	The identification of product status shall be maintained throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.		
	7.5.4 Customer property		
7.5.4q1	The organization shall exercise care with customer property while it is under the organization's control or being used by the organization.	Do you use any customer-owned property? (Product, packaging, drawings, tooling, gages...) (If so, ask questions below)	
7.5.4q2	The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product.	How do you ensure that customer-owned property is identified, verified, protected, and safeguarded?	
7.5.4q3	If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).	If any customer property is lost, damaged etc., how is it reported to the customer? Can you show me **records** regarding this?	
	NOTE Customer property can include intellectual property or confidential health information.		
	7.5.5 Preservation of product		
7.5.5q1 820.120a), b), c), d), e) 820.150, 820.130, 820.140, 820.160	The organization shall establish documented procedures or documented work instructions for preserving (preserve) the conformity of product during internal processing and delivery to the intended destination.	How do you preserve the conformity of product during internal processing and delivery? (Verify product throughout audit) Can you show me **documented work instructions or procedures** for this?	
7.5.5q2 7.5.5q1 820.120a), b), c), d), e) 820.150, 820.130, 820.140, 820.160	This preservation shall include identification, handling, packaging, storage and protection.	How do identification, handling, packaging, storage and protection address the preservation of product?	

7.5.5q3 7.5.5q1 820.120a), b), c), d), e) 820.150, 820.130, 820.140, 820.160	Preservation shall also apply to the constituent parts of a product.	Does this also apply to component parts?	
	The organization shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions.		
	Such special storage conditions shall be controlled and recorded (see 4.2.4).		
	7.6 Control of monitoring and measuring devices		
7.6q1 820.72a), b), 1), 2)	The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).	How do you determine the measurements to be taken and the measuring equipment needed to demonstrate conformity with requirements?	
7.6q2 820.72a), b), 1), 2)	The organization shall establish documented procedures (processes) to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.	What process is in place to ensure that measurements are taken per the requirements? Can you show me **documented procedures** for this?	

7.6q3a 820.72a), b), 1), 2)	Where necessary ensure valid results, measuring equipment shall a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded; b) be adjusted or re-adjusted as necessary; c) be identified to enable the calibration status to be determined; d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and storage.	a) How do you ensure that measuring and test equipment is calibrated or verified proper frequencies with NIST traceable standards? If no such standards exist, where do you **record** the basis used for calibration or verification? b) What process is used to adjust or re-adjust measuring and test equipment when needed? c) How are measuring tools identified to enable the calibration status to be determined? d) How do you safeguard measuring equipment from adjustments that would invalidate the measurement results? e) How do you ensure that measuring its test equipment is protected from damage and deterioration during handling, maintenance and storage?	
7.6q4 820.72a), b), 1), 2)	In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.	When equipment is found to be out of calibration, how do you assess and record the validity of the previous measuring results?	
7.6q5 820.72a), b), 1), 2)	The organization shall take appropriate action on the equipment and any product affected.	What actions do you take on the equipment and any product affected?	
7.6q6 820.72a), b), 1), 2)	Records of the results of calibration and verification shall be maintained (see 4.2.4).	Can I see your **records** of the results of calibration and verification?	
7.6q7 820.72a), b), 1), 2)	When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.	Do you use computer software for monitoring and measurement? If so, is its ability to perform that function confirmed prior to initial use and reconfirmed as necessary?	

	8 Measurement, analysis and improvement		
	8.1 General		
8.1q1	The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed a) to demonstrate conformity of the product, b) to ensure conformity of the quality management system, and c) to (continually improve) maintain the effectiveness of the quality management system.	How do you plan and implement measurement, analysis and improvement processes needed a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system? c) to (continually improve) maintain the effectiveness of the quality management system?	
8.1q2 820.250	This shall include determination of applicable methods, including statistical techniques, and the extent of their use.	How do you determine what monitoring measurement, and analysis methods to use, including statistical techniques? How do you determine the extent of their use?	
	NOTE National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.		

	8.2 Monitoring and measurement		
	8.2.1 (Customer satisfaction) Feedback		
8.2.1q1 820.198	As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to (customer perception as to) whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.	How do you obtain information about (customer perception as to) whether Organization has met customer requirements? How is this information used?	
	The organization shall establish a documented procedure for a feedback system [see 7.2.3 c)] to provide early warning of quality problems and for input into the corrective and preventive action processes (see 8.5.2 and 8.5.3).		
	If national or regional regulations require the organization to gain experience from the post-production phase, the review of this experience shall form part of the feedback system (see 8.5.1).		
	8.2.2 Internal audit		
8.2.2q1 820.22	The organization shall conduct internal audits at planned intervals to determine whether the quality management system a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and b) is effectively implemented and maintained.	Are internal audits being conducted at planned intervals? Do they determine whether the QMS conforms to the requirements of ISO 13485 and to the other requirements established by Organization? (Review records to demonstrate conformance) Do they determine whether the QMS is effectively implemented and maintained? (Review records)	
8.2.2q2 820.22	An audit program shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits.	Can you show me an audit plan that takes into consideration the importance of the processes and areas to be audited, and the results of previous audits?	
8.2.2q3 820.22	The audit criteria, scope, frequency and methods shall be defined.	Where are the audit criteria, scope, frequency and methods defined?	
8.2.2q4 820.22	Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.	Can you demonstrate that selection of auditors and the conduct of audits are objective and impartial, and that auditors don't audit their own work?	

8.2.2q5 820.22	The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.	Can you show me your internal audit **procedure**? Can you show me the **records** of internal QMS audits?	
8.2.2q6 820.22	The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.	Who ensures that actions are taken to eliminate detected nonconformities and their causes? Are they being taken care of in a timely manner? (verify with records)	
8.2.2q7 820.22	Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).	What activities are done to verify the actions taken, and how are the verification results reported?	
MDD	Do the internal audits cover all elements, aspects and activities according to ISO 13485 and are specific requirements of Annex II, 3 (Annex V, 3) of Medical Device Directive taken into consideration?		
	8.2.3 Monitoring and measurement of processes		
8.2.3q1 820.70a), 820.250	The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.	What methods are used to monitor and measure the QMS processes?	
8.2.3q2 820.70a), 820.250	These methods shall demonstrate the ability of the processes to achieve planned results.	Can you show that they have achieved the desired results?	
8.2.3q3 820.70a), 820.250	When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.	When the desired results are not achieved, what actions are taken to ensure that the product meets requirements?	
	8.2.4 Monitoring and measurement of product		
	8.2.4.1 General requirements		
8.2.4q1 820.80a), b), c), d), e), 820.250	The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met.	What characteristics are checked to verify that product requirements have been met?	
8.2.4q2 820.80a), b), c), d), e), 820.250	This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1) and documented procedures (see 7.5.1.1).	At what stages of the product realization process do monitoring and measuring activities take place? Can you show me **documented procedures** for monitoring and measurement of product?	

8.2.4q3 820.80a), b), c), d), e), 820.250	Evidence of conformity with the acceptance criteria shall be maintained.	How is evidence of conformity with acceptance criteria maintained?	
8.2.4q4 820.80a), b), c), d), e), 820.250	Records shall indicate the person(s) authorizing release of product (see 4.2.4).	Can you show me **records** that indicate who has authorized release of product to the next stage of the process?	
8.2.4q5 820.80a), b), c), d), e), 820.250	Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed (unless otherwise approved by a relevant authority and, where applicable, by the customer).	How do you ensure that product is not released until the all requirements have been met? If product must be released prior to this, how is it approved?	

	8.2.4.2 Particular requirement for active implantable medical devices and implantable medical devices		
	The organization shall record (see 4.2.4) the identity of personnel performing any inspection or testing.	Can you show me **records** showing the identity of personnel performing inspection or testing?	
	8.3 Control of nonconforming product		
8.3q1 820.90a), b)	The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.	How do you ensure that nonconforming products are identified and controlled to prevent unintended use or delivery? (Verify product throughout audit)	
8.3q2 820.90a), b)	The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.	Can you show me a **documented procedure** defining the controls for dealing with nonconforming product? Does it show responsibilities/authorities?	
8.3q3 820.90a), b)	The organization shall deal with nonconforming product by one or more of the following ways: a) by taking action to eliminate the detected nonconformity; b) by authorizing its use, release or acceptance under concession (by a relevant authority and, where applicable, by the customer); c) by taking action to preclude its original intended use or application.	When you have nonconforming product, what methods do you use to deal with it?	
	The organization shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met.		
	Records of the identity of the person(s) authorizing the concession shall be maintained (see 4.2.4).	Can you show me **records** of the identity of personnel authorizing concessions?	
8.3q4 820.90a), b)	Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).	Can you show me **records** of NC material and any actions taken? Are there any **records** of concessions obtained?	
8.3q5 820.90a), b)	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.	When nonconforming product is corrected, can you demonstrate that it is re-verified to ensure it conforms to requirements?	
8.3q6 820.90a), b)	When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.	When nonconforming product is detected after shipment, what actions are taken, such as containment? (Verify corrective action records)	

	If product needs to be reworked (one or more times), the organization shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.	Can you show me rework **work instructions** approved by same authority as the original work instruction?	
	Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented (see 4.2.3 and 7.5.1).	Can you show me **records** of determination of adverse effects of rework? Was the determination made prior to authorization of the work instruction?	
	8.4 Analysis of data		
8.4q1 820.250	The organization shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.	What data is collected and analyzed to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of its effectiveness can be made? Can you show me **documented procedures** that describe this activity?	
8.4q2a 820.250	The analysis of data shall provide information relating to a) (customer satisfaction) feedback (see 8.2.1), b) conformity to product requirements (see 7.2.1), c) characteristics and trends of processes and products including opportunities for preventive action, and d) suppliers.	What information does this analysis provide relating to: - (customer satisfaction) feedback? (5.6) - conformity to product requirements? (See 5.6) - characteristics and trends of processes and products? (See 5.6) - suppliers? (See 7.4.1)	
	Records of the results of the analysis of data shall be maintained (see 4.2.4).		

	8.5 Improvement		
	8.5.1 (Continual improvement) General		
8.5.1q1 820.20c) 820.198	The organization shall (continually improve the) identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.	Can you demonstrate that Organization's QMS effectiveness continually improves? Can you demonstrate that Organization identifies and implements changes to ensure continued QMS effectiveness? What tools do you use? (See 5.6, 8.2.2, 8.4, 8.5.2, 8.5.3)	
	The organization shall establish documented procedures for the issue and implementation of advisory notices.	**documented procedures**	
	These procedures shall be capable of being implemented at any time.		
	Records of all customer complaint investigations shall be maintained (4.2.4).	**records**	
	If investigation determines that the activities outside the organization contributed to the customer complaint, relevant information shall be exchanged between the organizations involved (see 4.1).		
	If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4).	**Record**	
	If national or regional regulations require notification of adverse events that meet specified reporting criteria, the organization shall establish documented procedures to such notification to regulatory authorities.	**documented procedures**	
	8.5.2 Corrective action	**8.5.2 Corrective action**	
8.5.2q1 820.100	The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence.	Do corrective actions records identify and address root cause(s)? (Do root causes match actions?)	
8.5.2q2 820.100	Corrective actions shall be appropriate to the effects of the nonconformities encountered.	Are actions taken appropriate to the severity of the problem?	

8.5.2q3 820.100	A documented procedure shall be established to define requirements for a) reviewing nonconformities (including customer complaints), b) determining the causes of nonconformities, c) evaluating the need for action to ensure that nonconformities do not recur, d) determining and implementing action needed, including, if appropriate, updating documentation (see 4.2), e) (records) recording of the results of any investigation and of action taken (see 4.2.4), and f) reviewing the corrective action taken and its effectiveness.	Can you show me a **documented procedure** defining requirements for each of the following? a) reviewing nonconformities (including customer complaints) b) determining the causes of nonconformities c) evaluating the need for action to ensure that nonconformities do not recur d) determining and implementing action needed e) records of the results of any investigation and of action taken f) reviewing the corrective action taken and its effectiveness	
8.5.2q4 820.100	e) (records) recording of the results of any investigation and of action taken (see 4.2.4), and	Can you show me **records** of investigation and corrective actions taken?	
MDD	Does the manufacturer maintain a systematic procedure for a surveillance system after production?		
MDD	Does this surveillance system comply with the requirements of the Medical Device Directive?		
MDD	Are procedures implemented, documented and maintained to inform the competent authority about any incidents which are subject to report (see requirements of MDD)?		
	8.5.3 Preventive action	**8.5.3 Preventive action**	
8.5.3q1 820.100	The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.	How do you determine potential nonconformities to take action one? Do preventive action records identify and address root cause(s)?	
8.5.3q2 820.100	Preventive actions shall be appropriate to the effects of the potential problems.	Are actions taken appropriate to the severity of the problem?	

8.5.3q3 820.100	A documented procedure shall be established to define requirements for a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, d) (records) recording of the results of any investigation and of action taken (see 4.2.4), and e) reviewing preventive action taken and its effectiveness.	Can you show me a **documented procedure** defining requirements for each of the following? a) determining potential nonconformities and their causes, b) evaluating the need for action to prevent occurrence of nonconformities, c) determining and implementing action needed, f) (records) recording of the results of any investigation and of action taken (see 4.2.4), and d) reviewing preventive action taken and its effectiveness.	
8.5.3q4 820.100	d) (records) recording of the results of any investigation and of action taken (see 4.2.4), and	Can you show me **records** of preventive actions taken?	

Additional audit checklist questions

Q#	Requirement Text	Audit Question	Objective Evidence